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PATENT TRADEMARK OFFICE

Docket No.: 4305/1J396US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

John S. HAURUM et al.

Serial No.: TO BE ASSIGNED

Group Art Unit: TO BE ASSIGNED

Filed: Concurrently Herewith

Examiner: TO BE ASSIGNED

For: **A POLYCLONAL ANTIBODY COMPOSITION FOR TREATING ALLERGY**

Hon. Commissioner of
Patents and Trademarks
Washington, DC 20231

Sir:

PRELIMINARY AMENDMENT

Please amend this application as follows prior to examination.

IN THE SPECIFICATION

On page 1, after the Title please insert:

-- CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority under 35 U.S.C. §120 from U.S. Provisional Application No. 60/211,981, filed June 16, 2000, the entire disclosure of which is incorporated by reference herein.--

IN THE CLAIMS

Please amend Claims 5, 6, 9, 13, 14 and 18-24 as follow:

5. (Amended) A pharmaceutical composition according to claim 1, which composition is free of the allergen to which the antibody is reactive or binds.

6. (Amended) A pharmaceutical composition according to claim 1 comprising at least one pharmaceutically acceptable excipient capable of effecting topical application of said recombinant polyclonal antibody or said mixture of individual monoclonal antibodies or said isolated or purified polyclonal antibody.

9. (Amended) A pharmaceutical composition according to claim 1, which is provided as a solution, dispersion, powder or in the form of microspheres.

13. (Amended) A pharmaceutical composition according to claim 1, wherein the allergen is an allergen of house dust mites, e.g. Dermatophagoides farinae or D. pteronyssimus; dander from cat, dog or horse; tree pollen, e.g. pollen from birch (Betula alba), alder, hazel, oak, willow, plane, beech, elm, maple, ash,

mugwort (*Artemisia*) and hornbeam; grass pollen, e.g. pollen from timothy grass (*Pheleum pratense*), blue grass (*Poa pratense*), rye grass (*Lolium perenne*), Orchard grass (*Dactylis glomerata*), ragweed (*Ambrosia artemisiifolia*), sweet vernal grass (*anthoxanthum odoratum*), and rye (*Secale cereale*); or fungi (e.g. *Alternaria*, *Aspergillus*, *Cladosporium* and *Penicillium*).

14. (Amended) A pharmaceutical composition according to claim 1, comprising the recombinant polyclonal antibody or the mixture of monoclonal antibodies or the isolated or purified polyclonal antibody in an amount in the range of $1\mu\text{g}$ to 1g , preferably $1\text{-}1000\mu\text{g}$, more preferably $2\text{-}500\mu\text{g}$, even more preferably $5\text{-}50\mu\text{g}$, most preferably $10\text{-}20\mu\text{g}$ per unit dosage form.

18. (Amended) The use according to claim 15, wherein the polyclonal antibody is a recombinant polyclonal antibody.

19. (Amended) The use according to claim 15, wherein the polyclonal antibody is a mixture of individual monoclonal antibodies.

20. (Amended) The use according to claim 15, wherein the polyclonal antibody is an isolated or purified polyclonal antibody.

21. (Amended) The use according to claim 15, wherein the composition is intended for topical administration to the oropharynx, nasal cavity,

respiratory tract, gastrointestinal tract, conjunctival mucosa, vagina, urogenital mucosa, or for dermal application.

22. (Amended) The use according to claim 15, wherein the polyclonal antibody is included in the composition in an amount in the range of 1 μ g to 1g, preferably 1-1000 μ g, more preferably 2-500 μ g, even more preferably 5-50 μ g, most preferably 10-20 μ g per unit dosage form.

23. (Amended) A method of preventing or treating allergy, which comprises administering to a patient in need thereof a composition according to claim 1, comprising a sufficient amount of a polyclonal antibody capable of reacting with or binding to an allergen to which the patient has shown or is predisposed to develop an allergic reactions.

24. (Amended) A method of inducing tolerance to an allergen which comprises administering to a patient who would untreated be likely to show allergic reaction to the allergen a composition according to claim 1 comprising a sufficient amount of a polyclonal antibody capable of reacting with or binding to the allergen and induce tolerance to the allergen in the patient.

REMARKS

Claims 5, 6, 9, 13, 14 and 18-24 have been amended to eliminate multiple claim dependency. This amendment broadens the claims. Entry of this amendment is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "S. Peter Ludwig", written over a horizontal line.

S. Peter Ludwig
Reg. No. 25,351
Attorney for Applicant(s)

Dated: May 25, 2001

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PATENT TRADEMARK OFFICE

Docket No.: 4305/1J396US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: John S. HAURUM et al.

Serial No.: Not yet assigned

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Examiner: N/A

For: **A POLYCLONAL ANTIBODY COMPOSITION FOR TREATING ALLERGY**

MARKED UP VERSION OF THE CLAIMS
IN PRELIMINARY AMENDMENT FILED MAY 25, 2001

Hon. Commissioner of
Patents and Trademarks
Washington, DC 20231

May 25, 2001

Sir:

IN THE CLAIMS

Please amend Claims 5, 6, 9, 13, 14 and 18-24 as follow:

5. (Amended) A pharmaceutical composition according to [any of

claims 1-4] claim 1, which composition is free of the allergen to which the antibody is reactive or binds.

6. (Amended) A pharmaceutical composition according to [any one of claims 1-5] claim 1 comprising at least one pharmaceutically acceptable excipient capable of effecting topical application of said recombinant polyclonal antibody or said mixture of individual monoclonal antibodies or said isolated or purified polyclonal antibody.

9. (Amended) A pharmaceutical composition according to [any of claims 1-8] claim 1, which is provided as a solution, dispersion, powder or in the form of microspheres.

13. (Amended) A pharmaceutical composition according to [any of claims 1-12] claim 1, wherein the allergen is an allergen of house dust mites, e.g. Dermatophagoides farinae or D. pteronyssimus; dander from cat, dog or horse; tree pollen, e.g. pollen from birch (Betula alba), alder, hazel, oak, willow, plane, beech, elm, maple, ash, mugwort (Artemisia) and hornbeam; grass pollen, e.g. pollen from timothy grass (Pheleum pratense), blue grass (Poa pratense), rye grass (Lolium perenne), Orchard grass (Dactylis glomerata), ragweed (Ambrosia artemisiifolia), sweet vernal grass (anthoxanthum odoratum), and rye (Secale cereale); or fungi (e.g. Alternaria, Aspergillus, Cladosporium and Penicillium).

14. (Amended) A pharmaceutical composition according to [any of claims 1-13] claim 1, comprising the recombinant polyclonal antibody or the mixture of monoclonal antibodies or the isolated or purified polyclonal antibody in an amount in the range of 1 μ g to 1g, preferably 1-1000 μ g, more preferably 2-500 μ g, even more preferably 5-50 μ g, most preferably 10-20 μ g per unit dosage form.

18. (Amended) The use according to [any of claims 15-17] claim 15, wherein the polyclonal antibody is a recombinant polyclonal antibody.

19. (Amended) The use according to [any of claims 15-17] claim 15, wherein the polyclonal antibody is a mixture of individual monoclonal antibodies.

20. (Amended) The use according to [any of claims 15-17] claim 15, wherein the polyclonal antibody is an isolated or purified polyclonal antibody.

21. (Amended) The use according to [any of claims 15-21] claim 15, wherein the composition is intended for topical administration to the oropharynx, nasal cavity, respiratory tract, gastrointestinal tract, conjunctival mucosa, vagina, urogenital mucosa, or for dermal application.

22. (Amended) The use according to [any of claim 15-21] claim 15, wherein the polyclonal antibody is included in the composition in an amount in the range of 1 μ g to 1g, preferably 1-1000 μ g, more preferably 2-500 μ g, even more

preferably 5-50 μg , most preferably 10-20 μg per unit dosage form.

23. (Amended) A method of preventing or treating allergy, which comprises administering to a patient in need thereof a composition according to [any of the claims 1-14] claim 1 comprising a sufficient amount of a polyclonal antibody capable of reacting with or binding to an allergen to which the patient has shown or is predisposed to develop an allergic reactions.

24. (Amended) A method of inducing tolerance to an allergen which comprises administering to a patient who would untreated be likely to show allergic reaction to the allergen a composition according to [any of the claims 1-14] claim 1 comprising a sufficient amount of a polyclonal antibody capable of reacting with or binding to the allergen and induce tolerance to the allergen in the patient.